

# SPL Bulletin

A Downstream Use of SPL Subgroup Publication

June 2013

Issue 2

## Welcome

### New Members

Bernie Coney  
Jacqueline Davis  
David Hernandez  
Grace Min  
Kristina Stracco

Number of Unique Product  
SPL Files on DailyMed:

**51,271**

(at time of publication)

Number of Pharm Class  
SPL Files on DailyMed:

**2,331**

(at time of publication)

Number of Billing Unit SPL  
Files on DailyMed:

**51,724**

(at time of publication)

### Co-chairs of Downstream Use of SPL Subgroup

Virginia Hogan  
John Lorenc  
Jacquelyn Mohns  
Lonnie Smith

We're on the web:

Downstream Use of SPL  
Subgroup's Web Page

## 50,000 Product SPL & Counting



*Interesting Note: An Edocrin SPL file was one of the very first SPL documents posted on DailyMed.*

In November 2005, a lone SPL file awaited the arrival of other SPL documents with information about the thousands of approved brand and generic human prescription drug products commercially marketed at the time. For several months, downstream users of SPL continuously

checked National Library of Medicine's DailyMed website for more structured data to download and import into their healthcare information systems. Finally, in 2006, as more SPL document authors learned the SPL standard, hundreds of SPL files joined that lone SPL document on DailyMed.

Time-travel to mid-2009 and you will witness the beginning of exponential increases in the amount of SPL as files with information for products such as OTC and animal drugs started appearing on DailyMed.

The over 50,000 product SPL files currently posted on DailyMed reflects the determination of SPL document authors to contribute to the improvement of patient care via the provision of up to date product data in SPL format for download into healthcare information systems.

## NSDE

Over a year ago, CMS announced its intent to utilize downstream SPL data. The May 14, 2012, CMS memo notified all part D sponsors that, beginning September 1, 2012, the FDA's Comprehensive NDC SPL Data Elements (NSDE) file would be used in the editing of prescription drug event submissions. The NSDE file, which is updated once each business day, contains the following

types of data that is extracted from SPL files submitted to FDA: item code (NDCs, NHRICs, and ISBTs), ) proprietary name, dosage form, marketing category, application number or citation, product type, and marketing start date. The NDC11 and, in some cases, the package marketing end date, is derived from SPL data transmitted to FDA.

During the summer of 2013, a column with billing units data from the billing unit indexing SPL will be added to the NSDE file.

The NSDE file and a copy of the CMS NSDE memo is accessible via this web page hyperlink: <http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/ucm240580.htm>.